

Appl. No. 10/798,677  
Amdt. C dated June 5, 2008  
Reply to non-final O.A. of March 21, 2008

### **Remarks**

#### **I. Status.**

Claims 1-79, 81-101, 103-108, 111, 113-125, and 127-137 are pending and at issue, claims 80, 102, 109, 110, and 126 having been previously canceled. The present amendment further cancels claim 112, reinstates previously canceled claim 126 as claim 137, and amends claims 1, 3, 4, 11, 12, 30, 54, 111, 113, and 127-131.

The undersigned thanks Examiner Chao for the courtesies extended during a telephonic interview on May 30, 2008, between the examiner and the undersigned, during which the parties discussed the patentability of the application claims over the applied references and it was suggested by the examiner to leave the independent claims substantially unamended and submit the following remarks for further consideration. The following remarks summarize and amplify the substance of the interview.

#### **II. Traversals of Rejections and Arguments for Patentability.**

The applicants traverse the rejection of the claims at issue under 35 U.S.C. §103(a) as obvious over Shechtman et al. U.S. Patent No. 6,524,260 ("Shechtman") in view of Bova et al. U.S. Patent No. 6,390,982 ("Bova") and Galloway, Jr. et al. U.S. Patent No. 7,072,707 ("Galloway"), or further in view of any of various combinations of Pearlman U.S. Patent No. 7,141,019 ("Pearlman"), Ustuner U.S. Patent No. 6,746,402, Sliwa, Jr. et al. U.S. Patent No. 6,511,427, Danisch U.S. Patent No. 5,321,257, Walbrink et al. U.S. Patent No. 5,449,356, Magasi U.S. Patent No. 4,826,492, and Touzawa et al. U.S. Publication No. 2003/0198372.

The applied references do not disclose or render obvious a system for determining a global position of an anatomical structure of a patient's body, as recited by claims 1-22, that includes a surgical navigation system, a substrate adapted to be removably mounted to an outer surface of a user's body, a sensor attached to the substrate that can be tracked by the surgical navigation system, a positional device attached to the substrate, and a structure adapted to be mounted to a finger of the user, wherein the structure is movable in relation to the sensor, and wherein the positional device is adapted to determine a relative position of the structure in relation to the positional device, and further comprising a first circuit for calculating a global position of a point on the anatomical structure by correlating a position of the sensor and the relative position of the structure.

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Further, the applied references do not disclose or render obvious a method for determining a position of a point on an anatomical structure of a patient using a surgical navigation system, as recited by claims 23-53, comprising the steps of mounting a substrate in a removable manner to an outer surface of a user's body, the substrate having a positional device and a sensor that can be detected by the surgical navigation system, covering a fingertip of the user with a finger mounted structure, wherein the finger mounted structure is movable in relation to the sensor, and wherein the positional device is adapted to determine a relative position of the finger mounted structure with respect to the positional device, placing the finger mounted structure on the point of the anatomical structure to be determined, calculating the relative position of the finger mounted structure in relation to the positional device, and determining the position of the point from the relative position of the finger mounted structure.

Further still, the applied references do not disclose or render obvious a system for determining a global position of an object, as recited by claims 54-73, wherein the system includes a navigation system, a substrate comprising a glove adapted to be mounted to an outer surface of a user's body, a sensor attached to the substrate that can be tracked by the navigation system, a positional device attached to the substrate, and a structure mounted to a finger of the glove, wherein the structure is movable in relation to the sensor, and wherein the positional device is adapted to determine a relative position of the structure in relation to the positional device, and further comprising a first circuit for calculating a global position of a point on the object by correlating a position of the sensor and the relative position of the structure.

Yet further, the applied references do not disclose or render obvious a method for determining a position of a point on an object using a navigation system, as recited by claims 74-79 and 81-94, that includes the steps of mounting a glove on a user's hand, wherein the glove has a positional device that determines a position of a point on the object and a sensor that can be detected by a surgical navigation system, disposing a finger mounted structure on a finger of the glove capable of communicating with the positional device, wherein the finger mounted structure is movable in relation to the sensor, placing the finger mounted structure on the point of the object to be determined, and determining the position of the point.

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Furthermore, the applied references do not disclose or render obvious an apparatus for determining a position of a point on an anatomical structure, as recited by claims 95-101 and 103-108, that includes a glove adapted to be mounted on a hand of a user, a sensor and a magnetic tracker attached to the glove, a structure comprising a magnetic sensor mounted to a finger of the glove, wherein the magnetic sensor is movable in relation to the sensor, and wherein the magnetic tracker determines a relative position of the magnetic sensor, and further comprising a first circuit for calculating the position of the point on the anatomical structure by correlating a position of the sensor and the relative position of the magnetic sensor.

Additionally, the applied references do not disclose or render obvious a method for determining a position of a point on an anatomical structure through a small incision opening, wherein the point is obstructed from the incision, as recited by claims 111, 112-125 and 127-137, that includes the steps of mounting a substrate in a removable manner to an outer surface of a user's body, covering a tip of the user's finger with a finger mounted pointer that has a rigid tip, wherein the finger mounted pointer is capable of communicating with an external positional device mounted on the substrate and the external positional device is associated with a sensor mounted on the substrate that can be detected by the surgical navigation system, and wherein the finger mounted pointer is movable in relation to the sensor, manipulating the finger mounted pointer so that the rigid tip is in contact with the point to be determined, determining the relative position of the finger mounted pointer in relation to the sensor with the external positional device, determining the global position of the sensor, and determining the global position of the point from the relative position of the finger mounted pointer and the global position of the sensor.

**A. Summary of Specific Applied References.**

Shechtman discloses a contour mapping system with a workstation 10 that determines the position of a rigid probe 2 within a magnetic field generated by a field generator 9. Referring to FIG. 2, the rigid probe 2 is "constructed such that when it is grasped by a user's hand, the outer tip of the index finger of the user's hand is at a predetermined position with respect to a position sensor [4] carried by the probe." Shechtman column 4, lines 58-61. Shechtman describes the use of the rigid probe 2 as follows:

When probe 2 is used, as shown in FIG. 2, for mapping the curvature of a person's

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spine, the movements of the position sensor 4, which correspond to the movements of the user's index finger and thereby of the curvature of the person's spine, are tracked by a position tracking system included within a data processor in a workstation 10. Column 5, lines 44-49.

In another embodiment, "FIG. 4 illustrates a probe, therein generally designated 30, used with a reference sensor, generally designated 32, attached to [a patient's] body at a fixed and known location with respect to a predetermined reference point of the spine 34." Column 6, lines 43-47. The reference sensor 32 is used in combination with the separate probe 30 so that "the position tracking system [included within the workstation 10] will track the movements of the probe 30 with respect to the reference 32; and since the position of the reference 32 is known with respect to the spine 34, the tracked movements of the probe trace the curvature of the spine." Column 6, lines 47-51. Shechtman describes the specific benefits of having a reference sensor 32 attached to the patient's body as follows:

Such an arrangement makes the system sensitive only to the changes in position of the probe 30 with respect to the reference 32, and thereby enables the system to ignore changes in position of the person's body generally in space. The system illustrated in FIG. 4, therefore, is particularly useful for displaying the dynamic movements of the spine during body movements, e.g., forward and sideward bending movements. Column 6, lines 50-57.

In another embodiment of FIG. 4, the "[r]eference sensor 32 . . . may be the magnetic field generator itself which also thereby serves as a reference with respect to probe 30." Column 6, lines 59-63.

Bova discloses an ultrasound imaging system 10 that includes a reference device 14 that "is preferably secured directly to a stable (such as skeletal) part of the patient" and has patient position markers 16. Bova column 5, lines 63-67. The system 10 further includes a "3D ultrasound probe 22 . . . [that] provides 3D imaging data to the processor 20." Column 6, lines 24-27. "A reference device 24 is fixed to the probe 22 and has probe position markers 26." Column 6, lines 27-28. "The markers 16 and 26 are tracked using an infrared (IR) camera system 28." Column 6, lines 33-35. The IR camera system 28 is connected to the processor 20, which first converts the imaging data from the ultrasound probe 22 into data relative to the frame of reference of the device 14 using the

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position of the markers 16, 26. Column 6, lines 35-38. Next, the processor 20 converts the imaging data into data relative to the fixed frame of reference of the IR camera system 28. Column 6, lines 38-43. In another embodiment, the fixed frame of reference provided by the markers 16 and the reference device 14 is provided instead by markers 116 attached to a body frame 134, which immobilizes the patient.

Galloway discloses a system that registers surgical data with preoperative data and with a position of an instrument. Referring to FIG. 3, one embodiment of the system includes an ablative instrument 320, an optical tracking sensor 325, and a reference emitter 330. The ablative instrument 320 has a rigid body with multiple infrared light emitting diodes ("IRED") attached thereto. The optical tracking sensor 325 receives infrared light from the ablative instrument 320 and the reference emitter 330 to track the position of the ablative instrument 320 in relation to the reference emitter 330.

**B. The reference sensor 32 of Shechtman is not "a substrate adapted to be removably mounted to an outer surface of a user's body," as argued in the pending Office action.**

The applicants respectfully traverse the argument in the pending Office action that the reference sensor 32 of Shechtman discloses a substrate adapted to be removably mounted to an outer surface of a user's body and that the probe 30 discloses a structure adapted to be mounted to a finger of the user. See pending Office action page 5. More specifically, the reference sensor 32 and the probe 30 are not mounted to or located on a single user, as argued in the pending Office action. In fact, the reference sensor 32 of Shechtman is required to be attached to the body of the patient in order to provide a fixed reference point with respect to the patient's spine while the probe 30 is mounted to a finger of the user to trace the contour of the patient's spine.

Consequently, the reference sensor 32 does not disclose or render obvious a substrate for mounting to the user, as recited variously by the claims at issue. Therefore, the applicants respectfully request reconsideration and withdrawal of the rejections and allowance of the claims at issue.

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**C. The proposed modification of Shechtman to place the reference sensor 32 on the same substrate as the fingertip device 30 would ignore an explicit claim limitation that a structure, a magnetic tracker, or a finger mounted pointer is movable in relation to a sensor, as recited variously by the claims at issue.**

As discussed above, the examiner asserts that the reference sensor 32 and the probe 30 of Shechtman disclose the substrate and the structure, respectively, recited by the claims at issue. However, the reference sensor 32 is not adapted to be removably mounted to an outer surface of a user's body. Applicants traverse the argument on page 6 of the pending Office action that "one of ordinary skill in the art would know to place the reference sensor [32] on the same substrate as the fingertip device [30]," because such proposed modification ignores a limitation in the claims at issue that variously recites a structure, a magnetic tracker, or a finger mounted pointer that is movable in relation to a sensor. Further, claims 1-22, 54-73, 95-101, 103-108, 111, 113-125, and 127-137 recite a sensor attached to or mounted on a substrate or glove and claims 23-53, 74-79, and 81-94 variously recite a substrate or glove having a sensor.

Consequently, if the reference sensor 32 were to be integrated with the fingertip device 30, as suggested by the examiner, then the fingertip device 30 would not be moveable in relation to a sensor attached to or otherwise included with the reference sensor 32, as recited by the claims at issue. More specifically, the only detailed disclosure in Shechtman of the fingertip device 30 is the disclosure of rigid probes 2 and 3 that already include sensors 4 and 22, respectively, which are not movable in relation to the probes. Therefore, one of ordinary skill in the art would recognize that the proposed modification to place the reference sensor 32 on the probe 30 would also result in the probe 30 being fixed in relation to any sensor integrated therewith.

Therefore, Shechtman cannot be modified as argued by the examiner because the claims at issue recite that the structure, magnetic tracker, or finger mounted pointer is movable in relation to the sensor. Therefore, the applicants respectfully request reconsideration and withdrawal of the rejections and allowance of the claims at issue.

**D. The applied references do not disclose or render obvious a positional device as recited by the claims at issue.**

Claims 1-22 recite a substrate adapted to be removably mounted to an outer surface of a

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user's body and a positional device attached to the substrate. Claims 23-53 recite mounting a substrate in a removable manner to an outer surface of a user's body, the substrate having a positional device. Claims 54-73 recite a substrate comprising a glove adapted to be mounted to an outer surface of a user's body and a positional device attached to the substrate. Claims 1-73 also recite that the positional device is adapted to determine a relative position of a structure in relation or with respect to the positional device.

Further, claims 74-79 and 81-94 recite mounting a glove on a user's hand, wherein the glove has a positional device that determines a position of a point on an object.

Still further, claims 95-101 and 103-108 recite a glove adapted to be mounted on a hand of a user and a magnetic tracker attached to the glove that determines a relative position of a magnetic sensor

In addition, claims 111, 113-125 and 127-137 recite mounting a substrate in a removable manner to an outer surface of a user's body with an external positional device mounted on the substrate and determining a relative position of a finger mounted pointer in relation to a sensor with the external positional device.

The applicants respectfully traverse the assertion in the pending Office action that the reference sensor 32 in FIG. 4 of Shechtman discloses the positional device or magnetic tracker recited by the above noted claims. See pending Office action page 5. Specifically, the reference device 32 is incapable of determining a relative position of a separate structure but only provides a reference point from which other calculations are performed to map a contour of the patient. Instead, Shechtman discloses the workstation 10 and, in particular, the position tracking system included within the data processor in the workstation 10 that determines the position of the reference sensor 32 and the probe 30. However, the workstation 10 is completely separate from a user and, therefore, is not adapted to be mounted to a user, as required by the claims at issue. Further, while Shechtman does disclose that the reference sensor 32 can be a magnetic field generator, such magnetic field generator still only serves as a reference point from which other calculations are performed by the workstation 10 to map a contour of the patient and is distinguishable from the magnetic tracker that determines a relative position of a magnetic sensor, as recited, for example, by claim 95.

Further, Bova does not disclose or render obvious a positional device or magnetic tracker as

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recited by the above noted claims. Instead, Bova is similar to Shechtman and includes the processor 20 connected to the IR camera system 28 that determines the relative positions of various markers on the reference device 14, the ultrasound probe 22, and/or the body frame 134. Like the workstation 10 of Shechtman, the processor 20 of Bova is completely separate from a user and, therefore, is not adapted to be mounted to a user, as required by the claims at issue.

Still further, none of the remaining applied references disclose or render obvious a positional sensor, as recited by the claims at issue. Therefore, the applicants respectfully request reconsideration and withdrawal of the rejections and allowance of the claims at issue.

**E. Shechtman teaches away from the proposed modification with the applied references and, further, the proposed modification would not improve Shechtman, as suggested in the pending Office action.**

As discussed in detail in prior Amendments A and B, Shechtman teaches away from removing the reference sensor 32 from the patient's body and placing the reference sensor 32 on the probe 30, because such modification would render Shechtman unsatisfactory for its intended purpose of providing a precise contour mapping system.

Specifically, Shechtman states that "FIG. 4 illustrates a probe, therein generally designated 30, used with a reference sensor, generally designated 32, attached to [a patient's] body at a fixed and known location with respect to a predetermined reference point of the spine 34." Shechtman column 6, lines 43-47. The reference sensor 32 is used in combination with the separate probe 30 so that "the position tracking system will track the movements of the probe 30 with respect to the reference 32; and since the position of the reference 32 is known with respect to the spine 34, the tracked movements of the probe trace the curvature of the spine." Column 6, lines 47-51. Such arrangement makes the system of Shechtman "sensitive only to the changes in position of the probe 30 with respect to the reference 32, and thereby enables the system to ignore changes in position of the person's body generally in space." Column 6, lines 50-54.

From the above statements, it is clear that the intended purpose of Shechtman is not merely "to map the position of an anatomical structure using the tip of the operator's finger," as asserted in the pending Office action, but to provide a precise contour mapping system that is "sensitive only to



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the changes in position of the probe 30 with respect to the reference 32." See pending Office action page 3; Shechtman column 6, lines 50-54.

Accordingly, the reference sensor 32 must be attached to the patient to provide a fixed reference point with respect to the patient's spine and the probe 30 must be separate from the reference sensor 32 to be able to trace the curvature of the patient's spine with reference to the fixed position of the reference sensor 32. Therefore, Shechtman teaches away from the proposed modification in the pending Office action, which ignores these clear requirements and erroneously argues that it would be obvious to remove the reference sensor 32 from the patient's body and place it on the probe 30, and which would, in fact, render Shechtman unsatisfactory for its intended purpose of providing a precise contour mapping system.

The applicants also traverse the arguments in the pending Office action that "Bova teaches a system and motivation that would only improve on Shechtman's invention by adding accuracy and reducing complexity by tracking the reference using an infrared system, [and] reducing any error that would occur as a result of the reference sensor moving slightly in relation to the fingertip device of item 30" and, therefore, that "one of ordinary skill in the art would know to place the reference sensor on the same substrate as the fingertip device so that the operator would not have to deal with two separate devices which are position independent." Pending Office action page 3. Specifically, these statements appear to disregard the fact that Bova actually teaches a more complex system than Shechtman in that Bova requires at least two separate devices that are position independent, i.e., the ultrasound probe 22 and at least one of the patient position markers 16 attached to the reference device 14 that is invasively secured to a skeletal structure of the patient or the markers 116 attached to the body frame 134 that immobilizes the patient. Further, Galloway does not provide any other relevant motivation but similarly teaches a tracking system that requires at least two separate devices, i.e., the ablative instrument 320 and a separate reference emitter 330 that are tracked by the optical tracking sensor 325 to determine the position of the ablative instrument 320 in relation to the reference emitter 330. Still further, the examiner has not pointed to any evidence that "tracking the reference using an infrared system" would actually be any more accurate or less complex than using the magnetic tracking system of Shechtman, nor does this statement appear to be particularly relevant to the claims at issue. Additionally, if the reference sensor 32 were to be placed on the probe 30,

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then there would be no reduction of "error that would occur as a result of the reference sensor moving slightly in relation to the fingertip device of item 30," because the reference sensor 32 would be fixed with respect to the probe 30, as discussed above. See pending Office action page 3.

Therefore, it is not obvious to not modify Shechtman with the teachings of Bova and Galloway as argued in the pending Office action to remove the reference sensor 32 and place it on the probe 30, because such modification ignores the teachings of the applied references that require a separate reference point to provide a precise contour mapping or tracking system.

The remaining applied references do not overcome the deficiencies pointed out above with respect to the proposed modification. Therefore, the applied references fail to support a *prima facie* case of obviousness of any of the claims at issue, and the rejections of all of the claims at issue as obvious thereover should be withdrawn and the claims allowed, notice of which is respectfully requested.

**F. Pearlman does not overcome the deficiencies pointed out with the proposed modification of Shechtman with the teachings of Bova.**

In light of the above, the applicants reiterate the arguments regarding Pearlman found in previous Amendment B dated January 18, 2008, which are hereby incorporate herein by reference.

**III. Conclusion**

For at least the above reasons, the applicants respectfully request reconsideration and allowance of the foregoing claims.

If there are any issues remaining that can be resolved by telephone, the examiner is invited to call the undersigned.

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**Deposit Account Authorization**

The Commissioner is hereby authorized to charge any deficiency in any amount enclosed or any additional fees which may be required during the pendency of this application under 37 CFR 1.16 or 1.17, except issue fees, to Deposit Account No. 50-1903.

Respectfully submitted,

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